

Remarks

Claims 2-4, 10-13, 15-17, 31 and 33-36 are pending in the application upon entry of the above amendment. Claims 34-36 have been withdrawn from consideration.

Claims 2, 3 and 33 have been amended to indicate that the starch utilized in the claimed methods is a waxy maize starch. This feature was stated in claim 14, which has now been cancelled. Further support for the amendment is found in the specification at page 14, lines 7-8 and 17-18. Corresponding amendments have been made in claims 4, 31 and 33-36.

Reconsideration and allowance is requested in view of the above changes and the following remarks.

Response to 35 U.S.C. 112 Rejection

Claims 2-4, 10-17, 31 and 33 have been rejected under 35 USC 112, 2nd paragraph, as being allegedly indefinite, due to the term "semi-crystalline". While applicants disagree with Examiner's characterization of indefiniteness, the rejection is moot in view of the above amendments.

Response to 35 U.S.C. 103 Rejections

Rejection of claims 2-4, 10-11, 13-16, 31 and 33 over Kaufman (US Pat. 5,605,893) in view of Anderson *et al.*

Claims 2-4, 10-11, 13-16, 31 and 33 stand rejected as allegedly obvious over Kaufman US Pat. 5,605,893, in view of Anderson *et al.*, *Starch* 54:401-409 (2002). The rejection alleges that Kaufman discloses a therapeutic food composition containing starch, preferably cornstarch, for treatment of diabetic and patients with glycogen storage diseases, but differs from the claimed invention insofar as it does not disclose a heat moisture-treated or annealing-treated, semi-crystalline starch.

Anderson is alleged to disclose heat moisture-treated waxy corn starch. The rejection notes that Anderson *et al.* does not disclose a method of treating hypoglycaemia in an individual in need of such treatment.

The rejection alleges that it would have been obvious to have selected a heat moisture-treated, semi-crystalline starch as a complex carbohydrate for inclusion in the food composition

of Kaufman, since heat moisture-treated, semi-crystalline starch is allegedly known in the art as allegedly disclosed by Anderson *et al.*

Claims 2 and 3 have been amended such that the administered therapeutic food composition comprises a waxy maize starch which is a heat moisture-treated starch or annealing-treated starch. The object of Anderson *et al.* is to provide a slowly digestible starch (SDS). Anderson *et al.* teaches the heat moisture treatment of non-waxy and waxy starches, for example rice, corn (corn = maize) and wheat with variable results. The treatment was only successful for waxy and non-waxy *rice* starch, there being no discernable effect on waxy and non-waxy wheat and *corn* starch. Heat moisture treatment of waxy and non-waxy corn starch did not result in significant decreases in starch digestibility.

The heat moisture treatment of starch in Anderson *et al.* is quite specific. The Anderson method involves the heating of starch at its melting point (1360°C to 1400°C) for 60 minutes. See Figure 1 of Anderson, and section 3.1 for interpretation of Figure 1. The present application teaches a quite different method of heat moisture treatment of starch that renders the treated starch with quite exceptional and unexpected properties.

The present application exposes moist starch to sub-melting temperatures [950C-1300C] for extended periods, e.g. up to 30 hours, typically 16-24 hours. This heat moisture starch treatment regime produces a starch with a quite unexpected glucose release profile once administered to subjects in need of controlling hypoglycaemia.

A paper co-authored by applicants and others, Bhattacharya *et al.*, "A Novel Starch for the Treatment of Glycogen Storage Diseases", *J. Inherit. Metab. Dis.* 30:350-357, 2007 (Appendix G to the *Amendment* filed September 16, 2009), compares heat moisture treated maize starch with untreated maize starch, and illustrates the following properties of the latter:

1. Blood glucose content is controlled over many hours thereby by controlling hypoglycaemia.
2. An initial "spike" in glucose release by native starch is reduced thereby providing better control of glucose release.
3. The duration of glucose release is prolonged to provide a sustained release pattern post administration.

4. Measurement of breath hydrogen, a measure of glucose fermentation, is significantly higher in those subjects receiving heat moisture treated starch indicating reduced colonic fermentation.

5. More rapid suppression of lactate production.

6. Improved insulin homeostasis.

There would have been no motivation for one skilled in the art to adopt a hydrothermally treated corn starch, either waxy or non-waxy, from Anderson *et al.* for use in the therapeutic food of Kaufman. The fact that heat moisture treatment of waxy and non-waxy corn starch did not result in significant decreases in digestibility in the disclosure of Anderson *et al.* would not have incentivized the skilled artisan to do anything further with that material, such as to utilize it as the basis of a therapeutic food composition for treatment of diabetic and patients with glycogen storage diseases. The skilled artisan would have perceived that if one were to have applied the teaching in Anderson *et al.* to waxy maize starch, the above beneficial properties could not have been obtained since Anderson *et al.* teaches that the heat moisture treatment regime as applied to waxy maize starch has no physical or biochemical effect on maize starch with respect to modifying glucose release. See the Anderson abstract. Anderson *et al.* teaches away from applying heat moisture treatment to waxy maize starch because the process, according to the Anderson *et al.* disclosure, has no effect on glucose release.

Accordingly, in the absence of any motivation to modify Kaufman in view of Anderson in the manner alleged by Examiner, it is respectfully submitted that methods and compositions of claims 2, 3, 31 and 33, as amended, would not have been obvious to one of ordinary skill in the art.

As to claim 31, Examiner continues to maintain that patentable weight need not be given to the non-functional descriptive matter in the claims, i.e., the printed instructions, absent a new and nonobvious functional relationship between the printed matter and the substrate, citing MPEP2106.01. There is indeed a new and unobvious functional relationship between the printed matter and the substrate. The printed matter provides instructions for treating hypoglycaemia or preventing or decreasing hypoglycemic episode(s) by ingesting the therapeutic food composition. For the reasons discussed above, the use of a waxy maize heat moisture-treated

starch or annealing-treated starch for the treatment of hypoglycemia is both novel and nonobvious. Hence, printed instructions directed to that use provide a new and nonobvious functional relationship between the printed matter and the composition contained in the kit.

The printed instructions must be given patentable weight. Those instructions therefore serve to distinguish the kit over the asserted prior art. Reconsideration and withdrawal of the rejection of claim 31 is respectfully requested.

Rejection of claims 2-4, 11-14, 17, 31 and 33 over Hansson *et al.* (WO 02/34271) in view of Anderson *et al.*

Claims 2-4, 11-14, 17, 31 and 33 have been rejected as allegedly obvious over Hansson *et al.* in view of Anderson *et al.* The rejection alleges that Hansson *et al.* discloses a composition of heat-treated starch for the prevention of hypoglycemia in patients with diabetes or liver disease, and discloses a method for stabilizing blood sugar levels and avoiding oscillation between unhealthy high and low blood sugar levels. The rejection acknowledges that Hansson *et al.* differs from the claimed invention insofar as it does not disclose a heat moisture-treated or annealing-treated, semi-crystalline starch. The rejection further notes that Anderson *et al.* does not disclose a method of treating hypoglycaemia in an individual in need of such treatment. Despite these deficiencies, Examiner alleges that it would have been obvious to one of ordinary skill in the art at the time of the invention to use a heat moisture-treated, semi-crystalline starch in the food composition of Hansson *et al.* since heat-moisture-treated, semi-crystalline starch is allegedly disclosed by Anderson *et al.*

For the same reasons provided above in response to the rejection of the claims over Kaufman in view of Anderson *et al.*, there would have been no motivation for one skilled in the art to adopt a hydrothermally treated corn starch from Anderson *et al.*, either waxy or non-waxy, for use as the starch in the food composition of Hansson *et al.* As indicated above, the failure of the heat moisture treatment of Anderson *et al.* to alter the digestibility of waxy and non-waxy corn starch would have been a disincentive to use that heat-moisture treated material as the basis of a therapeutic food composition for treatment of diabetic and patients with glycogen storage diseases. Based on the negative results of Anderson *et al.*, the skilled artisan would not have

been motivated to adopt the Anderson *et al.* heat-moisture treated maize starch for use as the starch in the Hansson *et al.* composition.

It is respectfully submitted that methods and compositions of claims 2-4, 10, 11, 13-16, 31 and 33, as amended, would not have been obvious to one of ordinary skill in the art over Hansson *et al.* in view of Anderson *et al.*

As to claim 31, for the reasons discussed above, the use of a waxy maize heat moisture-treated starch or annealing-treated starch for the treatment of hypoglycemia is both novel and nonobvious over the combination of Hansson *et al.* in view of Anderson *et al.* Hence, printed instructions directed to that use provide a new and nonobvious functional relationship between the printed matter and the composition contained in the kit.

The printed instructions must be given patentable weight, and therefore serve to distinguish the kit over the asserted prior art. Reconsideration and withdrawal of the rejection of claim 31 is respectfully requested.

Request for Rejoinder of Claim 34 (Group II), Claim 35 (Group III) and Claim 36 (Group IV)

Claims 34 and 35 are directed to a method of treating glycogen storage disease and liver disease, respectively. Claim 36 is directed to a method of treating Type I diabetes or Type II diabetes. The instant office action alleges that the claims are not linked by a special technical feature in view of Kaufman, and that the inventions of Groups I-IV fail to make a contribution over the prior art. The rejection alleges that Kaufman deprives the invention of novelty, and therefore defeats the existence of a special technical feature.

Claims 34, 35 and 36 have been amended to recite that the administered therapeutic food composition comprises waxy maize starch which is a heat moisture-treated starch or annealing-treated starch. This is the feature set forth in the other independent method claims in the application, claims 2 and 3. For the same reasons that Kaufman does not anticipate claims 2 and 3, it does not anticipate claims 34, 35 and 36. Indeed, as acknowledged in the Detailed Action, Kaufman does not disclose a heat moisture-treated or annealing-treated starch. Claims 34-36 recite the administration of a food composition comprising a waxy maize starch which is a heat

moisture-treated or annealing-treated starch. Thus, Kaufman does not anticipate any of the claims of the present application, and does not deprive the claimed invention of unity.

Moreover, for the reasons discussed above in connection with the rejection of claims 2 and 3, the therapeutic administration of a food composition comprising a waxy maize starch which is a heat moisture-treated or annealing-treated starch is not rendered obvious over the asserted prior art of record, alone or in any combination. The feature is a special technical feature which unifies the claims of the application. Rejoinder of claims 34-36 with the claims under examination is respectfully requested.

Conclusion

The claims remaining in the application are believed to be in condition for allowance. An early action toward that end is earnestly solicited.

Respectfully submitted,

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